



Gilead
Sciences Research
Scholars
Program in
Liver Disease

The Americas



GILEAD

Advancing Therapeutics.
Improving Lives.



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MISSION STATEMENT

The mission of the *Gilead Sciences Research Scholars Program in Liver Disease – The Americas* (the “program”) is to support innovative scientific research that will advance knowledge in the field of liver disease and provide support for research career development. Gilead Sciences, Inc. hopes that the research supported by these awards will enhance understanding of liver disease.

PROGRAM OVERVIEW

The *program* provides financial support to the institutions of 4 junior faculty researchers for a 2-year period. Each award is funded up to USD 130,000 (inclusive of any indirect costs), to be paid in annual installments of up to USD 65,000 per year for 2 years. Funding for the second year is contingent upon submission of a progress report by each junior faculty researcher and approval by the Chair of the *Scientific Review Committee* which oversees the *program*.

Recipients of these competitive awards under the *program* will be selected by a *Committee* (as defined below) comprised of leaders in the field of liver disease (the “*Scientific Review Committee*” or the “*Committee*”). The *Committee* will review complete applications and select research proposals based on their scientific merit, feasibility, and innovation. Announcement of Award Recipients will be made at an awards dinner hosted by the *Committee* and senior representatives from Gilead.

Applicants must meet the eligibility criteria in order to be considered for an award. Refer to the **Eligibility** section on page 4.

SCIENTIFIC FOCUS

The program is designed to support basic and clinical research in the field of liver disease. We strongly encourage proposals in clinical research. Areas of research may include, but are not limited to:

- Chronic viral hepatitis
- End-stage liver disease and its complications
- Non-viral chronic liver diseases
- Basic, clinical, and translational research related to liver disease
- Health economics outcomes research relating to liver disease

Awards granted under the *program* may not be duplicative of funding from institutional or hospital, other governmental, non-governmental, or industry sources. *Applicants* seeking an award for research projects that are currently receiving or may receive partial funding from other sources are required to submit appropriate evidence, including budget information related to the other sources, to demonstrate that there is no direct overlap in funding.

Proposals are reviewed by an independent Scientific Review Committee, (no Commercial involvement in review or selection, i.e., Marketing, Sales, and Commercial Strategy), and are reviewed based upon the criteria outlined in this brochure.

SCIENTIFIC REVIEW COMMITTEE

Applications will be reviewed by the *Committee* comprised of internationally recognized experts in basic and clinical research in the field of liver disease.

Chair:

Nezam Afdhal, MD
Professor of Medicine
Beth Israel Deaconess Medical Center
Boston, MA

Review Committee:

Michael R. Charlton, MD
Professor of Medicine
Director, Transplant Institute
Chief, Center for Liver Diseases
The University of Chicago
Biological Sciences
Chicago, IL

Jordan Feld, MD, MPH
Associate Professor of Medicine
University of Toronto
Toronto Centre for Liver Disease
University Health Network
Sandra Rotman Centre
for Global Health
Toronto, CANADA

Ariel E. Feldstein, MD
Professor of Pediatrics
Chief, Division of Pediatric
Gastroenterology, Hepatology,
and Nutrition
University of California, San Diego
San Diego, CA

Stephen A. Harrison, MD, FAASLD
Visiting Professor of Hepatology
Radcliffe College of Medicine
University of Oxford
Oxford, UK

David Kershenobich Stalnikowitz, MD, PhD
Director General
Instituto Nacional de Ciencias Médicas y
Nutrición Salvador Zubirán
MÉXICO

Mark Sulkowski, MD
Professor of Medicine
Medical Director, Viral Hepatitis Center
Johns Hopkins University
School of Medicine
Baltimore, MD



ELIGIBILITY

This award is intended for junior faculty who are in the early stages of their careers; specifically, the applicant may be the recipient of a career development (K) award or other mentored research award, but not an RO1 grant or equivalent. Applicants must meet the following requirements:

- Hold an MD, DO, PhD, or equivalent degree at time of award
- Be within 7 years of a faculty appointment in association with an academic research institution in Canada, Mexico, South America, or the United States at the time of application
- Have a strong career interest in liver disease
- Have a research mentor with extensive experience in the field of liver disease
- Be able to devote at least 50% of professional time to research (versus administrative, patient care, or teaching responsibilities)
- Be able to complete the proposed research within the 2-year award period, providing evidence (manuscript, presentation, or abstracts) for future research projects

Citizenship

Applicants must reside in Canada, Mexico, South America, or the United States.

An *applicant* must be a citizen or permanent resident of the country/region in which they propose to conduct the research, or otherwise hold a temporary study or nonimmigrant visa which allows legal residency in the country/region in which the research will be performed. Such visa must be valid for the two-year award period (January 2, 2019 – December 31, 2020)

CRITERIA FOR SELECTION

In their evaluation, the *Committee* will consider the following criteria:

Criterion 1: Evaluation of the *Applicant*

- Potential for a career in liver disease-related research
- Academic record
- Prior research experience and/or publications
- Clearly written presentation supporting the research need

Criterion 2: Scientific Environment and Institutional Support

- Letter of support from mentor which includes: mentor's track record of productivity, funding, and success with prior trainees; detailed description of the mentoring plan, including resources allocated to the proposed research project, provision of protected time and available laboratory facilities.
- The mentor is an independent investigator.

- The mentor has the experience to direct the proposed research training, as evidenced by the letter of support.
- The training plan is sufficient to facilitate the *applicant's* progress toward his/her research career goals.
- The proposed scientific environment contributes to the probability of success for the training experience.
- Letter of support from the department chair or division chief to document the institution is willing and has the ability to commit the resources necessary for the *applicant* to complete the proposed research, including sufficient protected time.

Criterion 3: Evaluation of the Proposal

- *Innovation and Significance:* The research proposal is new and original and addresses an important question/issue related to liver disease. The proposed study will have an effect on concepts, methods, and/or technologies related to liver disease research.
- *Approach:* The conceptual framework, design, methods, and analyses are adequately developed, well-integrated, well-reasoned, feasible (as determined by preliminary data or the expertise available), and appropriate to the aims of the project. The *applicant* acknowledges potential problem areas and considers alternative tactics.
- *Feasibility:* The project, as described in the submitted proposal and budget, can be accomplished within the timeframe of the award.

APPLICATION INFORMATION

Submission Deadline: Monday, July 1, 2019, 11:59 PM, Eastern Daylight Time.
No applications will be accepted after this date.

Applications must be completed online and submitted electronically with the required Supplementary Materials to <http://researchscholars.gilead.com>

If you have any questions, or require further information, please contact:
Research Scholars Program Coordinator
Telephone: 919-534-7663
E-mail: gileadsciences@bcdme.com

Application

Applicants must complete the online Application Form (all fields must be completed or *applicant* will not be able to submit) and include the following Supplementary Materials as specified:

- Research Abstract
- Research Proposal



- *Applicant's* biosketch, inclusive of publications, if applicable
- Mentor's biosketch
- Letter of support from mentor which includes: mentor's track record of productivity, funding, and success with prior trainees; detailed description of the mentoring plan, including resources allocated to the proposed research project, provision of protected time and available laboratory facilities
- Bibliography of relevant references (maximum of 20)
- Detailed budget and completed budget summary
- Acknowledgement of Indirect Costs Limitation, using the template provided on the *program* website
- Certification of Faculty Appointment from mentor is required and must be submitted with the application, using the template provided on the *program* website
- Current or Pending Funding, using the template provided on the *program* website
- Letter of support from the department chair or division chief that documents the institution is willing and has the ability to commit the resources necessary for the *applicant* to complete the proposed research, including sufficient protected time

GUIDELINES FOR THE RESEARCH PROPOSAL

The Research Proposal should be a clear and concise presentation of the *applicant's* proposed research.

The Proposal must include:

Research Abstract

Provide an abstract of no more than 325 words outlining the *applicant's* proposed research.

Research Proposal

Proposal must be single-spaced (using 11 point Arial font or larger) and limited to 5 pages total, not including the bibliography or budget. Research proposals over 5 pages will not be accepted.

The proposal must include:

1. Title of the proposed research
2. Description of research objectives, including relevant literature, specific aims, study design, methodology, data, and projected results

3. Discussion of the relevance of the proposed research to the objectives of the *program* (see **Scientific Focus** section on page 2)
4. Description of analytical methods (figures and tables should be included in the body of the text, where applicable)
5. Description of potential research challenges and possible approaches for overcoming them
6. Description of relevant past work by the *applicant*, including joint collaborations and references

BUDGET GUIDELINES

Indirect Costs:

- In an effort to maximize the research benefit of the award, the *program* encourages that every effort be made to minimize the utilization of the award to cover indirect costs. Indirect costs may not exceed 10% of the award value. This award is developed as a gift and is not considered a research grant.

Salaries:

- The *applicant* may allocate up to USD 50,000 per year in salary and fringe benefits support for the *applicant* and/or a technician.
- Salaries and fringe benefits for mentors, post-doctoral fellows, or students may not be included.

Supplies:

- Supplies such as disposables, chemicals, reagent kits, animals, etc, may be included.
- Equipment purchases with a single item value of greater than USD2,500 may not be included.

Travel:

- Up to USD 1,500 per year for *applicant's* travel to a scientific meeting for presentation of data may be included.

If the research project includes investigations on human subjects, a copy of the submission to the institutional review board (IRB) must be submitted prior to award. Award will be contingent upon IRB approval.

If the research project involves laboratory animals, researcher must certify that he/she will comply with all laws and regulations pertaining to care and use of animals in research prior to award.



PROGRAM TIMELINE

The timeline, from application submission to award disbursement, is below:

Application Deadline	Monday, July 1, 2019, 11:59 PM, Eastern Daylight Time
Applicant Notification	September 6, 2019
Award Disbursement	January 2, 2020

INQUIRIES/CONTACT INFORMATION

For general inquiries about the *Gilead Sciences Research Scholars Program in Liver Disease – The Americas*, please call or e-mail:

Gilead Sciences Research Scholars Program in Liver Disease – The Americas

Attn: Research Scholars Program Coordinator

Telephone: 919-534-7653

E-mail: gileadsciences@bcdme.com

FUNDING CONSIDERATIONS

If you are selected as an *award recipient*, you and your institution must agree to the following items, including, but not limited to:

■ **Exclusive Use of Funding**

In an effort to maximize the research benefit of the award, the *program* encourages that every effort be made to minimize the utilization of the award to cover indirect costs. Indirect costs may not exceed 10% of the award value. Funding is contingent upon *Committee* approval of the itemized budget.

■ **Use of Gilead Product**

Proposals utilizing Gilead product(s) are not eligible for funding through the Research Scholars Program. Proposals involving Gilead product(s) should be submitted under the Investigator-Sponsored Research Grant Program through our online portal: <http://www.gilead.com/research/investigator-sponsored>

■ **Progress Reports**

Submission of research progress and financial accounting reports for review by the *Committee* are required annually. Funding for the second year is contingent upon *Committee* Chair approval of the research progress report.

■ **Publications**

The support received under the *program* must be acknowledged in any publication or abstracts resulting from research funded by this award.

■ **Intellectual Property**

The host institution shall retain ownership of any invention conceived and reduced to practice during the length of the award resulting solely from the Research Plan. The invention shall be Confidential Information of the institution.

■ **Change of Award Recipient, Institution or Discontinuation**

The Research Scholars Program Coordinator must be notified immediately if the *award recipient* leaves the host institution or discontinues the research funded by the *program*. In the event *award recipient* moves to another institution, the award may be transferred or suspended at the sole discretion of the *Committee*. The new host institution must also agree to accept the terms and conditions of the existing award. In the event the host institution or *award recipient* is unable to complete the research or desires to discontinue the research before its completion, institution will be required to return all unexpended funds and any remaining award will be terminated.

Award recipients and their institutions will be required to enter into a written grant agreement with Gilead prior to receipt of funding.

PROGRAM AWARD RECIPIENTS

2018 Recipients

Adam Gehring, PhD

University Health Network

“Immunological Response to HBV Reactivation in Patients Stopping Nucleoside Analogue Therapy”

Ryan Schulze, PhD

Mayo Clinic

“A Novel Autophagic Mechanism Mediating Lipid Droplet Catabolism in Hepatocytes”

Dragana Kopanja, PhD

University of Illinois at Chicago

“Roles of FoxM1 in hepatic stellate cells in liver fibrosis and HCC development”

Michelle Long, MD

Boston University School of Medicine

“Determining the burden, heritability, and clinical implications of increased liver stiffness from fatty liver disease in older adults”



PROGRAM AWARD RECIPIENTS

2017 Recipients

Zongdi Feng, PhD

The Ohio State University College of Medicine
"Biogenesis and Functions of Secreted HBV RNA Particles"

Samar Ibrahim, MB, ChB

Mayo Clinic
"Mechanisms of Liver Injury in Nonalcoholic Steatohepatitis"

Daniela Sia, PhD

Icahn School of Medicine at Mount Sinai
"Biomarkers of Response to Immunotherapy in Liver Cancer"

Qian Xie, MD, PhD

James H. Quillen College of Medicine
East Tennessee State University
"Met-Targeting T Cell Therapy against Hepatocellular Carcinoma"

2016 Recipients

Jaime Chu, MD

Icahn School of Medicine at Mount Sinai
"Protein Glycosylation as a Novel Cellular Regulator of Hepatic Fibrosis"

Joanne Hsieh, PhD

College of Physicians and Surgeons of
Columbia University
"Hepatoprotective Mechanisms in TTC39B Deficiency"

Genta Kakiyama, PhD

Virginia Commonwealth University
"Elucidation of the Oxysterol Pathway and the Role of CYP781 in the Development of Liver Inflammation and Fibrosis"

Harmeet Malhi, MBBS

Mayo Clinic
"Endoplasmic Reticulum Stress and Sphingolipids in NASH"

PROGRAM AWARD RECIPIENTS

2015 Recipients

Andras Heczey, MD

Baylor College of Medicine

“Immunotherapy of Hepatocellular Carcinoma with Dual Specific Natural Killer T Cells”

Robert Christian Huebert, MD

Mayo Clinic

“Epigenetic Mechanisms of Biliary Regeneration”

Jennifer Layden, MD, PhD

Loyola University Chicago

“HBV Genotype E: Impact on Virologic and Serologic Host Response”

Massimiliano Paganelli, MD, PhD

CHU Sainte-Justine - Université de Montreal

“Autologous Transplantation of Induced Pluripotent Stem Cells-Derived Hepatocytes to Treat Hereditary Tyrosinemia Type 1”

2014 Recipients

Matthew Burchill, PhD

University of Colorado, Denver

“Immune Reconstitution and Reversal of Chronic Exhaustion Following Novel Directly-Acting Antiviral (DAA) Therapy”

Luke Engelking, MD, PhD

UT Southwestern Medical Center

“Site-2 Protease and Fatty Liver Disease”

William Osburn, PhD

Johns Hopkins University

“Pharmacological Targeting of the CCR5 Signaling Pathway to Enhance Anti-Hepatitis B Virus Immune Response”

Dean Yimlamai, MD, PhD

Boston Children’s Hospital

“Novel Regulators of Hippo Signaling in Liver Disease”



PROGRAM AWARD RECIPIENTS

2013 Recipients

Akiko Eguchi, PhD

University of California, San Diego

"The Development of Novel Diagnostic and Therapeutic Approaches for Non-Alcoholic Liver Disease Targeting Circulating Microparticles with Specific Antigens and MicroRNA Compositions"

Michel Fausther, PhD

University of Arkansas for Medical Sciences

"Ecto-5'-Nucleotidase/CD73 in the Pathogenesis of Liver Fibrosis"

Guisheng Song, PhD

University of Minnesota

"MicroRNA-206 as a Therapeutic Agent for Hepatocellular Carcinoma by Inhibiting Notch3"



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